

Remarks/Arguments:

Reconsideration of the application is requested.

Claims 1 to 30 are now in the application. Claims 1 to 12 are subject to examination and claims 13 to 25 have been withdrawn from examination. Claims 1 to 6 and 9 to 11 have been amended. Claim 26 to 30 have been added.

On pages 2 to 4 of the above-identified Office action, the Examiner issued a restriction requirement to Group I, claims 1 to 18, and Group II, claims 19 to 25. The Examiner also issued an election of species requirement to Group I for Species 1, a method of applying a clip with connected arms (Claims 1 to 12), and Species 2, a method of applying a clip with unconnected arms (Claims 13 to 18). Applicants hereby affirm election of the claims of Group I and Species 1. Upon allowance of a generic claim, applicants will be entitled to consideration of the claims of Species 2.

In item 1 on page 4 of the above-identified Office action, the Examiner objected to the specification and stated in support thereof:

Claim 1 (and subsequent claims) line 2 purports
that the clip slides over body tissue. The

Applicant does not show a picture of this or describe this process in the Specification. The word "slide" appears nowhere in the specification.

To even more clearly define the features of the claims of the instant application, applicants have changed "sliding" in claims 1, 6, 9, 10, and 11 to "advancing." Such advancement can clearly be understood through advancement of a clip pusher and, thereby, the clip (of FIGS. 17 to 24) within the various respective embodiments of the groove or guiding channel 54, 56, 54', 56', 54'', 56'' inside the jaws of the clip applier illustrated in FIGS. 10 to 14, particularly FIGS. 13 and 14, and as described, for example, on page 16, lines 11 to 17, page 17, lines 14 to 18, page 18, lines 9 to 21, page 19, lines 9 to 21, and page 20, lines 16 to 21. A clip shaped by such advancement is illustrated, for example, within groove 54', 56' in FIG. 5. These changes are neither provided for overcoming the prior art nor do they narrow the scope of the claim for any reason related to the statutory requirements for a patent. New FIG. 25 is being added to further diagrammatically illustrate features of the clip channels/grooves shown, for example, in FIGS. 4 to 9.

In item 2 on page 4 of the above-identified Office action, the Examiner objected to claim 5 because of an informality. An appropriate correction of the typographical error has been made.

In item 3 and 4 on page 5 of the above-identified Office action, claims 7, 10, and 11 have been rejected as being indefinite under 35 U.S.C. § 112, second paragraph.

More specifically, the Examiner first states that the phrase "said fundus" in line 3 of claim 7 lacks antecedent basis. Applicants respectfully disagree because there is only one instance of the word fundus in claims 1, 6, and 7 and that instance is in claim 7 itself. Nonetheless, to even more clearly define the features of claim 7, applicants have amended "said fundus" to "the invaginated fundus" as set forth earlier in claim 7.

The Examiner next states in claims 10 and 11 it "is unclear what the Applicant means by the phrase 'single clip applicator.' Does the Applicant mean to claim that there is only one [single] machine used to carry out the procedure, or does the Applicant mean to claims that the machine is only capable of applying one [single] clip?"

Applicants respectfully submit that the former interpretation is correct. As shown in the drawings and explained throughout the specification, the clip applier machine of the instant application performs all of the steps of sliding/advancing, clamping, and bending as set forth in claims 10 and 11, a separate grasping device is not needed. To even more clearly define the features of claims 10 and 11, the words "clip applier" have been replaced with the word "instrument."

It is accordingly believed that the specification and the claims meet the requirements of 35 U.S.C. § 112, second paragraph. The above noted changes to the claims are provided solely for the purpose of satisfying the requirements of 35 U.S.C. § 112. The changes are neither provided for overcoming the prior art nor do they narrow the scope of the claim for any reason related to the statutory requirements for a patent.

In items 5, 6, and 7 on pages 5 to 7 of the above-identified Office action, claims 1, 2, 5, 6, and 9 to 11 have been rejected as being fully anticipated by U.S. Patent No. 5,037,021 to Mills et al (hereinafter "Mills") under 35 U.S.C. § 102.

The rejection has been noted and the claims have been amended in an effort to even more clearly define the invention of the

instant application. Support for the changes is found, for example, from FIGS. 10 to 14 of the instant application.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 1 calls for, *inter alia*, a medical method, including:

advancing a clip over body tissue, the clip having two arms each having a respective piercing portion and a bridge coupling the two arms, such that the body tissue is located between the two arms and such that the clip applies force to the body tissue; and

subsequently bending the piercing portion of at least one through more than one half a thickness of the body tissue.

The Examiner states that FIGS. 5a to 5c of Mills and the description of Col. 6, lines 14 to 41, anticipates the invention of claim 1.

As is known, conventional staples (whether medical or clerical) pierce sheets of a material orthogonal to the plane of the sheets and bend the prongs that pierce through and already extend beyond the sheets in a direction along the

sheets to hold the sheets together and to, thereby, provide a compressing/holding force in the piercing direction, specifically, between the head of the staple and the bent-over tips.

FIGS. 5a to 5c of Mills clearly show that the Mills staple 209 is very similar to a staple from, for example, a SWINGLINE® desk stapler. In particular, the portion of the Mills staple that is to pierce the tissue enters the tissue perpendicular to the tissue fold while an anvil is placed on the opposite side of the tissue. Then, after completely piercing the tissue 216, the piercing portion is bent by the anvil 260 disposed on the other side of the piston 205. Simply put, the Mills stapler pierces straight portions orthogonally through the tissue and subsequently bends the straight portions with an external device (anvil 260) positioned on the opposite side of the tissue to cause the clenching force.

The piercing portion of the invention of claim 1, however, does not perform in this way. The clip of claim 1 is advanced over the body tissue in a longitudinal direction of the body tissue to be clipped. After advancing thereover, the piercing portion is caused to bend and, because of such bending, pierce the tissue. Because Mills does not disclose the features of claim 1, it cannot be said to anticipate claim 1.

To even more clearly define a longitudinally direction over which the clip is advanced at the folded body tissue and that the piercing portion is bent at an acute angle with respect to the longitudinal advancement direction claim 27 has been added. None of the cited references disclose or suggest the features of claim 27.

In items 8 and 9 on page 7 of the above-identified Office action, claims 1, 3, and 4 have been rejected as being fully anticipated by U.S. Patent No. 5,571,116 to Bolanos et al (hereinafter "Bolanos") under 35 U.S.C. § 102.

The Examiner contends that Bolanos discloses a method of sliding a clip over body tissue, the clip having, as shown in FIG. 31 therein, a bridge coupling two arms.

Just like Mills, Bolanos' staple 30 is similar to a conventional desktop stapler. Specifically, the portion of the staple 30 that is to pierce the tissue enters the tissue perpendicular to the tissue fold while an anvil 26 is placed on the opposite side of the tissue (see anvil recesses 33 in FIG. 6A, 6B, and 8). Then, after completely piercing the tissue, the pierced and orthogonally extending portion is bent by the anvil 26 disposed on the other side of the staple

ejector 28. See Bolanos at FIGS. 6B and 8. Nowhere does Bolanos disclose or suggest "advancing a clip over body tissue" as set forth in claim 1. Thus, Bolanos cannot anticipate claim 1 of the instant application.

Finally, in items 10 and 11 on pages 7 to 8 of the above-identified Office action, claims 1, 3, and 4 have been rejected as being fully anticipated by U.S. Patent No. 5,582,611 to Tsuruta et al (hereinafter "Tsuruta") under 35 U.S.C. § 102.

The Examiner contends that Tsuruta discloses, in FIGS. 42 and 43, a "clip (22) having two arms and bridge coupling the arms, as shown in Figure 61." Further, the Examiner contends that "the clip applies force to the body tissue" and that "[e]ach clip is bent through an entire thickness of the body tissue [see progression from Figure 42B to 42C]."

The rejection is entirely silent on the clip 22 advancing over any body tissue. This is because the Tsuruta clip does not disclose or suggest advancing the clip 22 over body tissue. Claim 1 clearly provides that a clip is advanced over body tissue. Because Tsuruta does not disclose or suggest such a feature, it cannot be said to anticipate claim 1.

FIGS. 82 and 83 of Tsuruta disclose a standard clip applier known to those having ordinary skill in the art. Such a clip applier, as described in Columns 28 to 29 therein, uses an electric cautery device after jaws 279 have clamped the clip 272 therebetween to cauterize the clamped portion and stop blood flow in the blood vessel clamped therebetween. This standard clip applier does not disclose or suggest piercing any portion of tissue.

Clearly, neither Mills, Bolanos, nor Tsuruta show a medical method as recited in claim 1 of the instant application.

In the election of species requirement, the Examiner stated that upon allowance of a generic claim, applicants would be entitled to consideration of the claims of Species 2. It is noted that the Species 2 feature of the method of applying a clip with unconnected arms can be read on claim 1 because claim 1 is broad enough to encompass both connected and unconnected clip arms. See new claim 28. Therefore, claim 1 is generic to Species 2 and claims 13 to 18 should be allowed as well.

In items 12 and 13 on pages 8 to 9 of the above-identified Office action, claims 7 and 8 have been rejected as being obvious over Mills in view of Bolanos under 35 U.S.C. § 103.

Insofar as claim 1 is believed to be allowable, and due to the fact that claims 7 and 8 ultimately depend upon claim 1, the rejections of these claims is now believed to be moot.

Applicants have added new claims 29 and 30. Support for these claims may be found at least from the original claims.

It is accordingly believed to be clear that none of the references, whether taken alone or in any combination, either show or suggest the features of claims 1, 27, or 29. Claims 1, 27, and 29 are, therefore, believed to be patentable over the art. The dependent claims are believed to be patentable as well because they all are ultimately dependent on claims 1, 27, or 29.

In view of the foregoing, reconsideration and allowance of claims 1 to 18 and 26 to 30 are solicited.

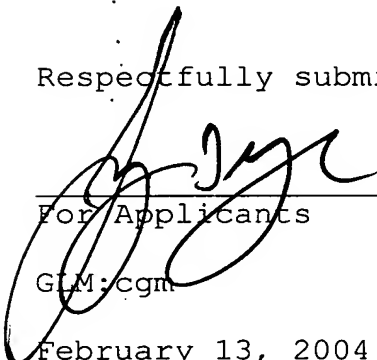
In the event the Examiner should still find any of the claims to be unpatentable, counsel would appreciate receiving a telephone call so that, if possible, patentable language can be worked out.

If an extension of time for this paper is required, petition
for extension is herewith made.

The extension fee for response within a period of three (3)
months pursuant to Section 1.136(a) in the amount of \$950.00
in accordance with Section 1.17 is enclosed herewith.

Please charge any other fees that might be due with respect to
Sections 1.16 and 1.17 to the Deposit Account of Lerner and
Greenberg, P.A., No. 12-1099.

Respectfully submitted,



For Applicants

GLM:cgm

Gregory L. Mayback
Reg. No. 40,719

February 13, 2004

Lerner and Greenberg, P.A.
Post Office Box 2480
Hollywood, FL 33022-2480
Tel: (954) 925-1100
Fax: (954) 925-1101